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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/638,173	08/06/2003	Robert Kain	ILLINC.026C1	3813

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EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

NOTIFICATION DATE	DELIVERY MODE
10/11/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/638,173	KAIN ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *60-117* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *60-117* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 15 August 2007 has been entered.

Status of the Claims

2. This action is in response to papers filed 15 August 2007 in which claims 60, 64-65, 69, 71, 75-76, 80, 3887-88, 92 were amended and claims 94-117 were added. The amendments have been thoroughly reviewed and entered.

The previous rejection in the Office Action dated 15 March 2007 under 35 U.S.C. 112, first paragraph is withdrawn in view of the amendments.

Applicant's arguments regarding the teaching of Felder have been thoroughly reviewed and are found persuasive. The previous rejections under 35 U.S.C. 103(a) are withdrawn in view of applicant's comments regarding Felder.

New grounds for rejection are discussed.

Claims 60-117 are under prosecution.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 109-111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 109-111 are indefinite because it is unclear how a method of sequencing further defines a method of making an array. The claims depend from Claim 94, which is drawn to a method of making an array composition. The claim includes steps of distributing genomic and non-genomic DNA on the substrate.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 60-61, 63, 66, 68-69, 71-7274, 77, 79-80, 82-84, 86, 89, 91-92 are rejected under 35 U.S.C. 102(e) as being anticipated by McDevitt et al (U.S. Patent No. 6,680,206, filed 16 July 1999).

Regarding Claims 60, 71 & 83, McDevitt et al disclose an array and method of making the array comprising a substrate having a surface (Fig. 3), a first assay location and second assay location on the surface, the assay locations separated from each other by channels that connect cavities in each row (#250, Fig. 3, Column 39, lines 15-34 and Column 40, lines 34-37), a first plurality of depressions in first and second assay locations and first and second microsphere populations randomly placed in the assay locations (Column 10, lines 13-16) and wherein the depressions have a single microsphere (Column, 9, lines 1-67).

Regarding Claims 61, 72 & 84, McDevitt et al disclose the array wherein substantially all the depression include a microsphere (Fig. 3).

Regarding Claims 63, 74 & 86, McDevitt et al disclose the array wherein the subpopulations are detectable in different channels (Column 24, line 10-Column 25, line 59 and Fig. 16).

Regarding Claims 66, 77 & 89, McDevitt et al disclose the array wherein the bioactive agent is DNA (Column 5, lines 45-65).

Regarding Claims 68, 79 & 91, McDevitt et al disclose the array wherein the substrate is enclosed within a hybridization chamber (Fig. 17, Column 26-27).

Regarding Claims 69, 80 & 92, McDevitt et al disclose the array wherein the hybridization chamber comprises a flexible membrane (Column 11, line s 40-44).

Regarding Claim 82, McDevitt et al disclose the array wherein the depressions are wells (Fig. 3).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 60-117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al (U.S. Patent No. 6,327,410, filed 11 September 1998) in view of Brown et al (U.S. Patent No. 5,807,522, issued 15 September 1998).

Regarding Claim 60, 64-65, 71, 75-76, 83, 87-88, 94-96, 100-101, Walt et al disclose an array and method of making the array comprising a substrate having a surface (Column 5,

lines 32-60), a first assay location and second assay location on the surface (Column 5, line 61-Column 6, line 30), wherein the substrate has a first plurality of depressions in first and second assay locations and first and second microsphere populations having both genomic and non-genomic (cDNA) DNA (Column 10, lines 26-31) randomly placed in the assay locations wherein the assay locations spatially identifiable manually (Column 18, line 59-Column 18, line 5) and wherein the depressions have a single microsphere (Column 6, lines 16-21).

Walt et al teach the assay locations spatially identifiable manually but they do not specifically teach the assay locations are separated.

However, array locations separated by gaskets were well known in the art at the time the claimed invention was made as taught by Brown et al.

Brown et al teach a substrate (e.g. glass slide) having a plurality of assay locations, each having a subpopulation of bioactive agents (e.g. genomic DNA, Example 1) wherein the assay locations are separated by a gasket e.g. rubber or silicone (Column 12) whereby the assay location are separately enclosed for hybridization (Column 13, lines 25-32).

Brown et al teach these barrier elements provide for multi-sample testing without cross contamination (Column 12, lines 61-67 and Column 15, lines 30-34). Walt clearly desires segregation of the subpopulations to provide spatial encoding of the microspheres and suggests manual techniques to do so (Column 18, line 59-Column 19, line 5). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the barrier elements of Brown et al to the substrate of Walt et al. One of ordinary skill in the art would have been motivated to do so based on the desired segregation of Walt et al and further for the expected benefit of providing for multi-sample testing without cross contamination between adjacent regions as taught by Brown (Column 12, lines 61-67 and Column 15, lines 30-34

Regarding Claim 61, 72, 84, 97, Walt et al teach the array and method wherein "substantially" all the wells have a microsphere (Fig. 7).

Regarding Claims 62, 73, 85, 98, Walt et al teach the array and method wherein the substrate is an optical fiber (Column 5, lines 57-60).

Regarding Claim 63, 74, 86, 99, Walt et al teach the array wherein the microspheres are in optical channels for detection (Column 13, lines 8-44, Column 16, lines 21-53).

Regarding Claim 66, 77, 89, Walt et al teach the array wherein the bioactive agent is DNA (Column 10, lines 28-35).

Regarding Claim 67, 78, 90, 102, Walt et al teach the array wherein the support is planar glass (Column 5, lines 57-60) and Brown et al teach the similar array wherein the support is a glass slide (Column 4, line 25).

Regarding Claims 68, 79, 91, 103, Walt et al teach the array is within a hybridization chamber (Fig. 4) and Brown et al teach the similar array within a hybridization chamber (Column 13, lines 26-32).

Regarding Claims 69-70, 80-81, 92-93, 104-105, Walt et al teach the array wherein the substrate comprises a membrane i.e. over the beads (Column 6, lines 45-47) and Brown et al teach the similar array wherein the substrate comprises a membrane wherein the barrier material flow into and seal the pores to create the barrier between the assay regions and separate hybridization regions within the hybridization chamber (Column 12). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the porous membrane of Brown to the substrate of Walt so as to facilitate barrier formation as taught by Brown (Column 12 and Column 13, lines 26-32).

Regarding Claim 106, Walt et al teach the depressions are wells (Column 6, lines 16-30).

Regarding Claim 107-108, Walt et al teach the method further comprising preparation of the DNA by PCR (Column 23, lines 5-8).

Regarding Claim 109-111, Walt et al teach the method wherein the bioactive agent is DNA (Column 10, lines 28-35) and the method includes sequencing (Column 24, lines 51-52).

While Walt et al teaches the array is used for sequencing, the sequencing practiced with the array produced by the method, does not further define the method of making the array. As such, the recited sequencing methods do not further define the method of Claim 94 for making the array.

Regarding Claims 112-117, Walt et al teach the arrays and methods wherein each subpopulation is randomly distributed such that members of each subpopulation are in multiple sub-bundles (Column 18, line 48-Column 19, line 53).

9. Claims 66-65, 67, 70, 75-76, 78, 81, 78, 81, 87-88, 90, 93, 94-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDevitt et al (U.S. Patent No. 6,680,206, filed 16 July 1999) in view of Brown et al (U.S. Patent No. 5,807,522, issued 15 September 1998).

Regarding Claims 66-65, 67, 70, 75-76, 78, 81, 78, 81, 87-88, 90, 93, 94-109, McDevitt et al disclose an array and method of making the array comprising a substrate having a surface (Fig. 3), a first assay location and second assay location on the surface, the assay locations separated from each other by channels that connect cavities in each row (#250, Fig. 3, Column 39, lines 15-34 and Column 40, lines 34-37), a first plurality of depressions in first and second assay locations and first and second microsphere populations randomly placed in the assay locations (Column 10, lines 13-16) and wherein the depressions have a single microsphere (Column, 9, lines 1-67).

McDevitt et al teach the array wherein a transparent cover plate is placed in contact with the upper surface of the substrate (e.g. glass, Column 8, line 64) whereby passages of fluid is restricted and further teach that channels selectively deliver reagents to rows of depressions/microspheres (Column 10, lines 51-67 and Column 40, lines 35-67). This clearly

suggests that the rows of assay regions are separated but the reference does not teach a gasket (e.g. silicon or rubber) providing separation.

However, array locations separated by gaskets were well known in the art at the time the claimed invention was made as taught by Brown et al.

Brown et al teach a substrate (e.g. glass slide) having a plurality of assay locations, each having a subpopulation of bioactive agents (e.g. genomic DNA, Example 1) wherein the assay locations are separated by a gasket e.g. rubber or silicone (Column 12) whereby the assay location are separately enclosed for hybridization (Column 13, lines 25-32). Brown et al further teach the method of making the array wherein the genomic DNA is prepared by PCR amplification and further sequence by physical mapping (Example 1).

Brown et al teach these barrier elements provide for multi-sample testing without cross contamination (Column 12, lines 61-67 and Column 15, lines 30-34). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the barrier elements of Brown et al to the substrate of McDevitt et al. McDevitt clearly suggests segregation of reagents to different regions by restrictive covering of the microsphere rows and by selective delivery via channels (Column 10, lines 51-67 and Column 40, lines 35-67). Hence, one of ordinary skill would have been motivated to add the barrier elements of Brown to the assay regions of McDevitt so as allow multi-sample testing without cross contamination between adjacent regions as taught by Brown (Column 12, lines 61-67 and Column 15, lines 30-34).

10. Claims 62, 73, 85, 94-99, 103-117 are rejected under 35 U.S.C. 103(a) as being unpatentable over McDevitt et al (U.S. Patent No. 6,680,206, filed 16 July 1999) in view of Walt et al (U.S. Patent No. 6,327,410, filed 11 September 1998).

Regarding Claims 62, 73, 85, 94-99, 102-117, McDevitt et al disclose an array and method of making the array comprising a substrate having a surface (Fig. 3), a first assay location and second assay location on the surface, the assay locations separated from each other by channels that connect cavities in each row (#250, Fig. 3, Column 39, lines 15-34 and Column 40, lines 34-37), a first plurality of depressions in first and second assay locations and first and second microsphere populations randomly placed in the assay locations (Column 10, lines 13-16) and wherein the depressions have a single microsphere (Column, 9, lines 1-67).

McDevitt et al teach the preferred substrate is integrated with the optical detector to allow evaluation of the reactions without separation of the reactants (Column 5, lines 12-21) but they do no teach a fiber optic substrate.

However, fiber optic substrate were well known and routinely practiced in the art at the time the claimed invention was made as taught by Walt et al.

Walt et al teach a similar array and method of making the array comprising a substrate having a surface (Column 5, lines 32-60), a first assay location and second assay location on the surface (Column 5, line 61-Column 6, line 30), wherein the substrate has a first plurality of depressions in first and second assay locations and first and second microsphere populations having genomic DNA (Column 10, lines 26-31) randomly placed in the assay locations wherein the assay locations spatially identifiable manually (Column 18, line 59-Column 18, line 5) and wherein the depressions have a single microsphere (Column 6, lines 16-21). Walt et al further teach the optical fiber substrate allows for "extremely high density array" fabrication (Column 5, lines 23-31). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the optical fiber substrate of Walt et al to the substrate of McDevitt et al. One of ordinary skill in the art would have been motivated to do so for the expected benefit of creating "extremely high density array" as desired in the art (Walt, Column 5, lines 23-31).

Conclusion

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

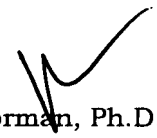
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



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Art Unit: 1634
October 1, 2007